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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,443	05/12/2006	Arnold Gloor	DSM-18-US	9839

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EXAMINER	
LILLING, HERBERT J	
ART UNIT	PAPER NUMBER
1657	
MAIL DATE	DELIVERY MODE
12/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,443	GLOOR, ARNOLD	
	Examiner	Art Unit	
	HERBERT J. LILLING	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-12,14,15,17,19 and 21-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1, 2, 4-12, 14-15, 17, 19 and 21-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Receipt is acknowledged an amendment response filed October 23, 2008 to a non-final rejection of the claimed subject matter.

2. Claims 1, 2, 4-12, 14-15, 17, 19 and new claims 21-41 are now pending in this application.

Claims 3, 13, 16, 18 and 20 have been cancelled.

3. In view of the amendments to the claims and new claims, the following restriction and election of species have been required which requirements are

in accordance with MPEP 811 [R-3] :

811 [R-3] **Time for Making Requirement**

37 CFR 1.142(a), second sentence, **>indicates that a restriction requirement "will normally be made before any action upon the merits; however, it may be made at any time before final action." This means the examiner should make a proper requirement as early as possible in the prosecution, in the first action if possible, otherwise, as soon as the need for a proper requirement develops.

Before making a restriction requirement after the first action on the merits, the examiner will consider whether there will be a serious burden if restriction is not required."

A serious burden has been severely placed on this Examiner in view of the amendments to the claims as well as new claimed inventions not submitted prior to the first office action. A search and examination was not performed on all of the inventions now pending in this application which new subject matter has been presented after a search and examination of the original claimed subject matter.

4. Thus, the following restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 4-12, 14-15, 17, 19 and 21, drawn to a process for the purification of **fermentatively produced riboflavin** that has at least one impurity which

is a DNA comprising the steps of-
(a) precipitating a first crystalline form of fermentatively produced riboflavin,
(b) isolating the first crystalline form of riboflavin,
(c) transforming the first crystalline form of riboflavin into a second crystalline form of riboflavin under conditions that decompose diluted DNA, and
(d) isolating the second crystalline form of riboflavin,
-wherein the first crystalline form of riboflavin is a riboflavin hydrate,
classified in class 435, subclass 262.

II. Claims 22-30, drawn to a process for the purification of riboflavin comprising the steps of:
(a) precipitating a first crystalline form of riboflavin,
(b) isolating the first crystalline form of riboflavin,
(c) transforming the first crystalline form of riboflavin into a second crystalline form of riboflavin under conditions that decompose diluted DNA, wherein the transforming is performed at a temperature of between 60°C and 75°C using (i) a mineral acid, (ii) a base, or (iii) an organic acid, and
(d) isolating the second crystalline form of riboflavin, provided that at ambient temperature the first crystalline form of riboflavin is thermodynamically less stable than the second crystalline form of riboflavin,
classified in class 544, subclass 251.

III. Claim 31, drawn to a process for the purification of riboflavin comprising the steps of:
(a) precipitating a first crystalline form of riboflavin,
(b) isolating the first crystalline form of riboflavin,
(c) transforming the first crystalline form of riboflavin into a second crystalline form of riboflavin under conditions that decompose diluted DNA, wherein a slurry comprising the first crystalline form of riboflavin is pumped continuously through a heat exchanger and further pumped through a tube equipped with a jacket heating and either a multistage stirring system or static mixers, and
(d) isolating the second crystalline form of riboflavin, provided that at ambient temperature the first crystalline form of riboflavin is thermodynamically less stable than the second crystalline form of riboflavin,
classified in Class 544, subclass 251

IV. Claims 32-40, drawn to a process for **decreasing the DNA content of riboflavin crystals** comprising the steps of:
(a) **fermentatively producing riboflavin** in a fermentation broth,
(b) precipitating and isolating riboflavin crystals of a first crystalline form of riboflavin from the fermentation broth,

(c) transforming the crystals of step (b) into a second crystalline form of riboflavin which is a thermodynamically more stable form of riboflavin than the first crystalline form, and
(d) isolating the crystals of step (c), classified in Class 435, subclass 66.

V. Claim 41, drawn to a process for removal of DNA from fermentatively produced riboflavin crystals comprising transforming a first crystalline form of riboflavin obtained from the fermentatively produced crystals into a second crystalline form of riboflavin, classified in Class 435, subclass 262.

Each of the above inventions is drawn to independent or distinct inventions that requires distinct searches in view of the fact that each of the above claimed inventions contains one or more patentably distinct process steps. The claimed subject matter of Invention I is drawn to a purifying a fermentative product whereas Invention II does not require that the product is a fermentative product for the purification of riboflavin containing diluted DNA. In addition, Invention I does not require that the transformation step for the purification of diluted DNA employing a specific temperature range in the presence of mineral acid, base or organic acid.

Invention III requires a heat exchanger for the transformation step of step (c) whereas Inventions I or II does not require this step for the transformation.

Invention IV is drawn to a process for decreasing DNA content of riboflavin crystals by transforming one type of riboflavin crystals by transformation of one type to another type of crystalline form which does not require specific process steps of Inventions I, II or III.

Invention V, is drawn to a process for removal of DNA by transforming one crystalline type to another which process does not specify any active process step for the transformation.

6. The above restriction for examination purposes as indicated is proper because all these inventions listed in this action **are independent or distinct for the reasons** given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their

different classification;

(b) the inventions have acquired a separate status in the art due to their

recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. This application contains claims directed to the following patentably distinct species :

A. Whereby the first crystalline form of riboflavin is:

a) riboflavin hydrate

ai) riboflavin monohydrate;

aii) riboflavin dihydrate;

aiii) other(s)-please specify;

aiv) any mixture of above.

B. Whereby the second crystalline form of riboflavin is:

a) riboflavin anhydrate I;

b) other(s) please specify;

c) mixture of above-please specify.

C. Whereby the conditions for transforming first form of riboflavin to a second form of riboflavin as noted by claim 1, claim 22 or claim 39, is selected from:

a) mineral acid,

b) base,

c) organic acid.

d) any combination of above-please specify.

D. Whereby the riboflavin is produced or obtained by:

a) fermentation;

b) organic synthesis;

c) other(s)-please specify;

d) any combination of above-please specify.

9. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic to all of the above requirements.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HERBERT J. LILLING whose telephone number is 571-272-0918. The examiner can normally be reached on WORK AT HOME MAXIFLEX.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JON WEBER can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit **1657**
December 19, 2008

/HERBERT J LILLING/
Primary Examiner Art Unit 1657